

CHARGE: 502(d)—the articles contained a chemical derivative of barbituric acid, and their labels failed to bear the name of the drug and, in juxtaposition therewith, the statement "Warning: May be habit forming."; and 505(a)—the articles were new drugs which may not be introduced into interstate commerce, since applications filed pursuant to law were not effective with respect to such drugs.

DISPOSITION: 8-8-60. Default—destruction.

### VIOLATIVE SALES OF PRESCRIPTION DRUGS

6384. Amphetamine sulfate (tablets and capsules). (F.D.C. No. 43626. S. No. 75-606 P.)

QUANTITY: Unknown quantity of tablets and capsules at Cairo, Ill.

SHIPPED: Prior to 10-26-59, from places outside the State of Illinois.

LIBELED: 10-28-59, E. Dist. Ill.

CHARGE: 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was not exempt from such labeling since the article was, or would, be in possession of persons not regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs and since the article was not to be dispensed as required by 503(b); 503(b)(1)—the article was a drug intended for use by man which, because of its toxicity or other potentiality for harmful effect and the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug and it was dispensed contrary to the provisions of such Section; and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12-15-59. Default—delivered to the Food and Drug Administration.

### DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS\*

6385. Dextro-amphetamine sulfate tablets and capsules and amphetamine sulfate tablets and capsules. (F.D.C. No. 43553. S. No. 75-813 P.)

QUANTITY: Unknown quantity of tablets and capsules at Wyatt, Mo.

SHIPPED: On an unknown date from Cairo, Ill., by Thurman L. Wilkerson, also known as Bo Wilkerson.

LIBELED: 10-28-59, E. Dist. Mo.

CHARGE: 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was not exempt from such labeling since the article was, or would be, in pos-

\*See also No. 6384.

session of persons not regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs and since the article was not to be dispensed as required by 503(b) ; and 503(b) (4)—the article was subject to the provisions of 503(b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11-24-59. Default—delivered to the Food and Drug Administration.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\***

6386. Amphetamine sulfate tablets. (F.D.C. No. 44199. S. Nos. 46-609/12 P.)

QUANTITY: 11 drums, each containing 50,000 tablets, 261 1,000-tablet btls., and 9 100-tablet btls., at Birmingham, Ala., in possession of Medical Specialties Corp.

SHIPPED: Between 7-21-58 and 11-25-59, from Houston, Tex., and Philadelphia, Pa.

LIBELED: 1-22-60, N. Dist. Ala.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since, although it was a prescription drug in possession of a wholesale distributor of prescription drugs, the exemption from bearing adequate directions for use had expired with respect to the article as provided in Regulation 1.106(b) because deliveries were, or would be, made contrary to 503(b).

DISPOSITION: 6-13-60. Default—destruction.

6387. Dainty-Maid Service. (Inj. No. 372.)

COMPLAINT FOR INJUNCTION FILED: 12-18-59, E. Dist. Mich., against Mrs. Wilma Becker, Detroit, Mich.

CHARGE: The complaint alleged that the defendant was engaged in selling and distributing an article designated by the name of "*Dainty-Maid Service*," consisting of a douche bag, a chrome-plated clamp, a box of "Dainty-Maid Personal Powder," a "Dainty-Maid Colonator," and a "Dainty-Maid 'Return-Flow' Earigator"; that the article was shipped to the defendant, from time to time, from Middlefield, Conn.; that while the article was being held for sale by the defendant after shipment in interstate commerce, the defendant, in the course of sales talks to prospective customers, caused oral representations to be made regarding the diseases, symptoms, and conditions for which the article was intended; and that defendant's act of making such oral representations resulted in the article being misbranded under 502(f) (1), in that the labeling failed to bear adequate directions for use in the treatment and prevention of the diseases, symptoms, and conditions for which the article was intended, namely, for preventing "female troubles," operations, including hysterectomies, cancer of the female parts, rot and decay in the vaginal tract, toxic poisons from entering the blood stream, and bladder trouble; for preventing and overcoming leukorrhea and painful or delayed menstruation; for overcoming Trichomonas infection and other conditions manifested by the presence of pus and inflammation, leukorrhea, sinus con-

\*See also Nos. 6384, 6385.